

serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon Receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for a hearing pursuant to § 1309.54. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to § 1309.51.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

#### HEARINGS

##### **§ 1309.51 Hearings generally.**

(a) In any case where the Administrator shall hold a hearing on any registration or application therefore, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551-559) and specifically by sections 303 and 304 of the Act (21 U.S.C. 823-824), by §§ 1309.52 through 1309.57, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41 through 1316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

##### **§ 1309.52 Purpose of hearing.**

If requested by a person entitled to a hearing, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration. Extensive argument should not be offered into evidence but rather presented in

opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

##### **§ 1309.53 Waiver or modification of rules.**

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

##### **§ 1309.54 Request for hearing or appearance; waiver.**

(a) Any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) Any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(c) If any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 fails to file a request for a hearing, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing, unless he shows good cause for such failure.

(d) If any person entitled to a hearing waives or is deemed to waive his or her opportunity for the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1309.57 without a hearing.

##### **§ 1309.55 Burden of proof.**

(a) At any hearing for the denial of a registration, the Administration shall

have the burden of proving that the requirements for such registration pursuant to section 303 of the Act (21 U.S.C. 823) are not satisfied.

(b) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) are satisfied.

**§ 1309.56 Time and place of hearing.**

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the FEDERAL REGISTER (unless expedited pursuant to Section 1309.44(c)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

**§ 1309.57 Final order.**

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the FEDERAL REGISTER his final order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which date shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Administrator finds that the public interest in the matter necessitates an earlier effective date, in which case the Administrator shall specify in the order his findings as to the conditions which led him to conclude that an earlier effective date was required.

MODIFICATION, TRANSFER AND  
TERMINATION OF REGISTRATION

**§ 1309.61 Modification in registration.**

Any registrant may apply to modify his or her registration to authorize the handling of additional List I chemicals or to change his or her name or address, by submitting a letter of request to the Drug Enforcement Administration, Chemical Registration/ODC, Post Office Box 2427, Arlington, Virginia

22202–2427. The letter shall contain the registrant's name, address, and registration number as printed on the certificate of registration, and the List I chemicals to be added to his registration or the new name or address and shall be signed in accordance with § 1309.32(g). No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 511) to the registrant, who shall maintain it with the old certificate of registration until expiration.

**§ 1309.62 Termination of registration.**

The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Administrator promptly of such fact.

**§ 1309.63 Transfer of registration.**

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administrator may specifically designate and then only pursuant to his written consent.

SECURITY REQUIREMENTS

**§ 1309.71 General security requirements.**

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of List I chemicals. Specific attention shall be paid to storage of and controlling access to List I chemicals as follows:

- (1) Chemicals shall be stored in containers sealed in such a manner as to indicate any attempts at tampering with the container. Where chemicals cannot be stored in sealed containers, access to the chemicals should be controlled through physical means or through human or electronic monitoring.
- (2) In retail settings open to the public where drugs containing List I